

### Remarks

Claims 1, 3 and 5-36 stand rejected under 35 U.S.C. § 103 over Gioffre et al. (U.S. 4,627,972) in view of Schobel (U.S. 4,687,662) or Rockliffe et al. (U.S. 4,471,871) or Andersen (U.S. 3,629,468).

Gioffre et al. disclose dentifrice compositions that provide an effervescent action and mechanical cleansing action when introduced to the oral cavity in the presence of water. Gioffre et al. disclose that the dentifrice composition includes an essentially anhydrous dentifrice base medium and an inorganic oxide material containing an effective amount of an adsorbed gas.

Schobel discloses effervescent compositions in the form of tablets or powders that dissolve rapidly in cold water to yield an effervescent solution containing a completely dissolved therapeutic agent. Schobel further describes a dissolution test that involves placing a tablet in water at 22°C and observing the various rates of dissolution of the tablet.

Rockliffe et al. disclose a method of packing dry-to-the-touch articles within a closed, moisture impervious container. Rockliffe et al. further disclose the article can be presented in the form of a sheet, a wad of fabric, a tablet, or a powder. Rockliffe et al. explain the purpose is to retain the included non-aqueous liquid of the article until the article is moistened with water to provide a variety of functions.

Andersen is directed to an effervescent tablet that can be placed directly in the mouth to provide a mouth wash. Andersen disclose placing the tablet in the mouth and adding a small amount of water to allow the effervescent reaction to commence.

Claim 1 is directed to a tablet that includes an effervescent composition that includes from 0.5 % by weight to about 10 % by weight menthol, from 0.5 % by weight to about 10 % by weight eucalyptus oil, and an effervescent agent that includes an acid and a base, wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution. Gioffre et al. do not teach a tablet that includes from 0.5 % by weight to about 10 % by weight menthol and from 0.5 % by weight to about 10 % by weight eucalyptus oil. Gioffre et al. also do not teach a tablet that dissolves in water having a temperature of at least 38°C to form a clear solution. Rather, Gioffre et al. list a

series of more than twenty flavoring agents and classes of flavoring agents that can be used in their dentifrice composition. Although menthol and eucalyptus oil are included in this laundry list, Gioffre et al. do not teach or suggest including both menthol and eucalyptus oil in the same composition. Gioffre et al. further disclose that their dentifrice compositions include liquids and solids that may be formed into a creamy mass that is extrudable. Gioffre et al. also disclose that in chewable dental tablets the solids and liquids are proportioned in amounts similar to dental creams and that a waxy matrix such as polyethylene glycol having a molecular weight of about 6000 is included to facilitate the formation of the tablet. Thus, Gioffre et al. disclose including a waxy matrix when forming a tablet. At no point do Gioffre et al. teach or suggest including menthol and eucalyptus oil in a tablet. Gioffre et al. further fail to teach or suggest including menthol, eucalyptus oil and an effervescent agent that includes an acid and a base in a tablet. Rather, to arrive at such a tablet from Gioffre et al., the skilled artisan would have to make a series of selections. In particular, the skilled artisan would have to 1) decide to include eucalyptus from among the more than twenty flavoring agents disclosed in Gioffre et al. (see, Gioffre et al., col. 4, lines 24-50), 2) decide to include a second flavoring agent when Gioffre et al. do not teach or suggest including more than one flavoring agent in their dentifrice composition, 3) select menthol from the list of more than twenty flavoring agents and classes of flavoring agents as a second flavoring agent when nothing in Gioffre et al. directs the skilled artisan to combine menthol and eucalyptus in the same composition and nothing in Gioffre et al. provides any reason to the skilled artisan to include more than one flavoring agent in their dentifrice composition, 4) decide to include from 0.5 % by weight to 10 % by weight menthol and from 0.5 % by weight to 10 % by weight eucalyptus in their composition, when Gioffre et al. disclose only that the flavor and sweetening agent together may comprise from about 0.1 to 10 % of the composition of Gioffre et al., 5) decide to include an optional gas generating agent, 6) decide to form the composition into a tablet instead of a powder or a paste, and then 7) decide to combine these ingredients in the form of a tablet that dissolves in water having a temperature of at least 38°C to form a clear solution, when Gioffre et al. explain that in chewable dental tablets a waxy matrix such as a polyethylene glycol having a molecular weight of about 6000 is included. Nothing in Gioffre et al.

provides the requisite direction to make these specific selections. Therefore the skilled artisan would have no reason to do so.

Gioffre et al. is further deficient for at least the following additional reasons. Gioffre et al. do not teach or suggest that it is important for their dentifrice or a tablet of their dentifrice to dissolve to a clear solution in water. Therefore the skilled artisan would have no reason to formulate the dentifrice composition of Gioffre et al. into a tablet that dissolves to a clear solution in water.

Schobel does not cure the deficiencies of Gioffre et al. As a preliminary matter, Applicants wish to note that they do not understand the manner in which Schobel is being combined with Gioffre et al. to render the tablet of claim 1 obvious. Accordingly, Applicants respectfully request that the next action provide clarification as to the manner in which Gioffre et al. and Schobel are being combined (see, MPEP 2143 *citing Ex parte Skinner*, 2 U.S.P.Q.2d 1788 (Bd. Pat. App. & Int. 1986) “When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teachings is proper”).

Notwithstanding the lack of clarity as to the basis for the rejection, Applicants now attempt to address the rejection. To establish a *prima facie* case of obviousness, the Examiner must show, inter alia, “some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art, would lead that individual to combine the relevant teachings of the references.” *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). “The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases, the nature of the problem to be solved.” *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the Examiner. *In re Piasecki*, 745 F.2d 1468, 223 U.S.P.Q. 785 (Fed. Cir. 1984). Combining prior art references without evidence of such a suggestion, teaching or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability, which is the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed

at the time." ). Here there is no such teaching, suggestion or motivation. Applicants note that Schobel does not teach or suggest forming dentifrice compositions into tablets. Schobel also does not direct the skilled artisan to make the selections set forth above from Gioffre et al. to arrive at the tablet of claim 1. In particular, Schobel does not teach or suggest including both eucalyptus and menthol in a single tablet. Schobel also does not teach or suggest how to formulate an oil such as eucalyptus oil into a tablet that dissolves to a clear solution. In addition, the function of Schobel's effervescent tablet is very different from that of the function of the dentifrice of Gioffre et al. Schobel discusses the use of effervescent compositions as a means of administering solubilized therapeutic agents (Schobel, col. 1, lines 24-27). Schobel further refers to ingesting therapeutic agents (Schobel, col. 1, lines 26-28). Schobel seeks to achieve a mechanism for solubilizing therapeutic agents in water. Gioffre et al., in contrast, are concerned with dentifrice compositions for cleansing teeth and the oral cavity (Gioffre et al., col. 1, lines 4-8). The compositions of Gioffre et al. are not intended to be ingested, and Gioffre et al. are not concerned with administering therapeutic agents via a solution. In addition, Gioffre et al. utilize their dentifrice composition for effervescent cleansing (see, Gioffre et al., col. 1, lines 59-61). Schobel does not teach or suggest that their tablets provide effervescent cleansing. Schobel also does not teach or suggest forming tablets that dissolve in water to provide effervescent cleansing. Therefore, the skilled artisan familiar with Gioffre et al. would have no reason to look to Schobel, would find Schobel to have no bearing on Gioffre et al., and further would find that Schobel provides no reason to modify the dentifrice of Gioffre et al. Accordingly, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel is unwarranted and Applicants respectfully request that it be withdrawn.

The December 22<sup>nd</sup> Office action appears to rely on a theory of inherency in asserting that the combination of Gioffre et al. and Schobel renders obvious the tablet of claim 1. In particular, Applicants understand the December 22<sup>nd</sup> Office action to take the position that the composition of Gioffre et al. would inherently dissolve in water having a temperature of at least 38°C to form a clear solution. As a preliminary matter, it is undisputed that Gioffre et al. do not actually teach the composition of the tablet claim 1. This is evidenced by the fact that the rejection of claim 1 over Gioffre et al. is under 35

U.S.C. § 103 --not § 102. An obviousness rejection is predicated on the fact that no single prior art reference teaches the claimed invention. An obviousness rejection relies upon a teaching, suggestion or motivation in a prior art reference or a combination of references to create a fictitious product. Therefore, in a rejection based on obviousness or a combination of two references, the product alleged to result from the combination never actually existed; therefore such a nonexistent product could not have had any inherent properties. Because the tablet of claim 1 is not actually taught by Gioffre et al., the tablet never actually existed. Rather it is a fiction that allegedly results from the combination of Gioffre et al. and Schobel. Therefore, there is no actual tablet to which to ascribe any properties, inherent or otherwise. For this reason, inherency is not a proper basis for a rejection under 35 U.S.C. § 103. Rather, inherency is appropriate only in rejections based on anticipation under 35 U.S.C. § 102. *See, e.g., Trintec Industries, Inc. v. TOP U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002), *citing In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (“Inherent anticipation requires that the missing descriptive material is “necessarily present,” not merely probably or possibly present, in the prior art. ... [I]nherency does not embrace probabilities or possibilities.”). For at least this additional reason, the rejection of claim 1 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen is unwarranted and Applicants respectfully request that it be withdrawn.

Claims 3, 5-20, 27-30 and 32-36 are distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the same reasons set forth above in distinguishing claim 1.

Claim 8 is further distinguishable over the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the following additional reasons. Claim 8 is directed to the tablet of claim 1 and further specifies that the tablet has a hardness of at least 15 kilopounds. Gioffre et al. do not teach a tablet that has any particular hardness. Gioffre et al. also fail to teach or suggest formulating a tablet that includes menthol and eucalyptus and that also exhibits a hardness of at least 15 kilopounds.

Schobel does not cure the deficiencies of Gioffre et al. Schobel does not teach or suggest formulating a tablet that includes menthol, eucalyptus oil and an effervescent

agent that includes an acid and a base to a hardness of at least 15 kilopounds. Nothing in the record establishes anything to the contrary. The secondary references of Rockliffe and Andersen do not cure the deficiencies of Gioffre et al. and Schobel. Applicants submit, therefore, that the rejection of claim 8 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen is unwarranted and respectfully request that it be withdrawn. Should this rejection be maintained, Applicants respectfully request that the next action indicate, by reference to column and line number, the location in the reference(s) of the requisite teaching, suggestion or motivation.

Claim 21 is directed to a tablet that includes an effervescent composition that includes from 0.5 % by weight to about 10 % by weight menthol, from 0.5 % by weight to about 10 % by weight eucalyptus oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 10 kilopounds and dissolving in water having a temperature of about 38°C in less than 120 seconds. The discussion set forth above regarding the deficiencies of Gioffre et al. in relation to claim 1 is incorporated herein. As set forth above, Gioffre et al. do not teach or suggest a tablet that includes menthol, eucalyptus oil and an effervescent agent that includes an acid and a base. Gioffre et al. also do not teach or suggest anything about the hardness of a tablet or a desirable tablet hardness. Gioffre et al. also do not teach or suggest that the dissolution time of a tablet is important.

Schobel does not cure the deficiencies of Gioffre et al. Schobel does not teach or suggest tableting dentifrices. Schobel also does not teach or suggest that tablet hardness is important. Schobel also does not teach or suggest that it is important for a dentifrice tablet to have a certain hardness. Schobel also does not teach or suggest selecting menthol, eucalyptus oil and an effervescent agent that includes an acid and a base for inclusion in a tablet and then formulating that tablet such that it exhibits a hardness of at least 10 kilopounds. Schobel also does not teach or suggest how to formulate a tablet of such a composition such that it will exhibit a hardness of at least 10 kilopounds and will dissolve in water in less than 120 seconds. Accordingly, Schobel provides the skilled artisan with no reason to *sua sponte* modify the dentifrice of Gioffre et al. and further fails to enable the skilled artisan to modify the disclosure of Gioffre et al. to somehow achieve the tablet of claim 21. Applicants submit, therefore, that the rejection of claim 21

under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen is unwarranted and Applicants respectfully request that it be withdrawn. Should this rejection be maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the passages in the cited references that are relied on in reaching the conclusion of obviousness of claim 21. Applicants further respectfully request that an explanation be provided in the next Office action explaining how the references are being combined and how the alleged teachings in the references render the tablet of claim 21 obvious.

Claims 22-28 are distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the same reasons set forth above in distinguishing claim 21.

Claim 31 is directed to a carbonated mouthwash that includes water, menthol, and eucalyptus oil. It is undisputed that neither Gioffre et al. nor Schobel nor Rockliffe et al. teach or suggest a mouthwash –let alone a mouthwash that includes menthol and eucalyptus oil. Applicants do not fully understand the basis for the conclusion in the December 22<sup>nd</sup> Office Action that it would have been obvious to form the composition of Gioffre et al. into a mouthwash. It appears that the December 22<sup>nd</sup> Office action takes the position that an effervescent tablet that dissolves in water to produce a solution is uniquely desirable for use as a mouthwash and cites the passage at column 1, lines 24-33 of Andersen to support this position (see, December 22<sup>nd</sup> Office action, page 4, third full paragraph). Nothing in either Gioffre et al. or the cited Andersen passage teaches or suggests that the mere fact that a tablet can dissolve in water to form a clear solution renders it uniquely suited for use as a mouthwash. Moreover, as established above, it is not the case that the composition of Gioffre et al., when formulated as a tablet, will necessarily (i.e., inherently) form a clear solution. In addition, nothing in either Gioffre et al. or Andersen directs the skilled artisan to select menthol and eucalyptus oil and formulate the same into a carbonated mouthwash. The proposed combination thus fails to render obvious the mouthwash of claim 31. Applicants submit, therefore, that the rejection of claim 31 under 35 U.S.C. § 103 over Gioffre et al. in view of Andersen is unwarranted and respectfully request that it be withdrawn. To the extent this rejection is maintained, Applicants respectfully request that the next action identify, by reference to

column and line number, the passages in the cited references that are relied on in reaching the conclusion of obviousness of claim 31. Applicants further respectfully request that an explanation be provided in the next Office action explaining how the references are being combined and how the alleged teachings in the references render the mouthwash of claim 31 obvious.

Claims 33 and 35 are further distinguishable over the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the following additional reasons. Claim 33 is directed to a method of using the tablet of claim 1, where the method includes dissolving the tablet in water to form a clear solution and inhaling vapors emitted by the solution. Neither Gioffre et al. nor Schobel, nor Radcliffe nor Andersen teach or suggest dissolving a tablet in water to form a clear solution and inhaling vapors emitted by the solution. Nothing in the record establishes anything to the contrary. Applicants submit, therefore, that the record fails to establish a *prima facie* case of the obviousness of claim 33. Accordingly, the burden of persuasion has not shifted to Applicants and the rejection of claims 33 and 35 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen cannot stand. Applicants respectfully request that the rejection be withdrawn. To the extent this rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the passages in the cited references that are relied upon in reaching the conclusion of obviousness of claim 33. Applicants further respectfully request that the next action provide an explanation as to the manner in which the specific references are being combined and how the alleged teachings in the references render the method of claim 33 obvious.

Claim 36 is further distinguishable over the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen for at least the following additional reasons. Claim 36 depends from claim 33 and further specifies that the water is boiling water. Neither Gioffre et al. nor Schobel nor Rockliffe nor Andersen teach or suggest dissolving a tablet in boiling water –let alone dissolving a tablet in boiling water to form a clear solution and then inhaling vapors emitted by the solution. Nothing in the record establishes anything to the contrary. Accordingly, the proposed combination of Gioffre et al. in view of Schobel or Rockliffe or Andersen fails to teach a required element of



claim 36. Applicants submit, therefore, that the record fails to establish a *prima facie* case of the obviousness of claim 36. Accordingly, the burden of persuasion has not shifted to Applicants and the rejection of claim 36 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen cannot stand; Applicants respectfully request that the rejection be withdrawn. To the extent this rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the passages in the cited references that are relied upon in reaching the conclusion of obviousness of claim 36. Applicants further respectfully request that the next action provide an explanation as to the manner in which the specific references are being combined and how the alleged teachings in the references combine to render the method of claim 36 obvious.

Applicants now address the statements in the December 22<sup>nd</sup> Office action regarding the temperature of the water. There is no teaching or suggestion in any of the cited references of boiling water, a method that includes dissolving a tablet in boiling water, or a method that includes inhaling vapors. Applicants are not clear as to the basis relied upon to support the rejection of claim 36 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel or Rockliffe or Andersen; however, it appears that the Examiner may be relying on “official notice” of an alleged “well known fact” under MPEP 2144.03 to support the rejection. Applicants note that official notice without documentary evidence to support an Examiner’s conclusion of obviousness is permissible only in some circumstances (see MPEP 2144.03 A). In addition, official notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. See *Id.* (“The notice of facts beyond the record that may be taken by the Examiner must be ‘capable of such instant and unquestionable demonstration as to defy dispute.’”) As the MPEP admonishes, “It is never appropriate to rely solely on ‘common knowledge’ in the art without evidentiary support in the record, as the principal evidence upon which a rejection . . . [is] based.” MPEP 2144.03 A citing *In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001). To the extent that the Examiner is taking “official notice” of an alleged “well known fact” under MPEP 2144.03 to support the rejection, Applicants respectfully request that the next action

include sufficient documentary evidence establishing that it is well known to dissolve a tablet having the composition of claim 1 in boiling water and then to inhale vapors emitted by the resulting solution.

Claim 34 is directed to a method of using the tablet of claim 1 that includes dissolving the tablet of claim 1 in water to form a clear solution and gargling with the solution. Gioffre et al. do not teach or suggest anything about gargling. Gioffre et al. also do not direct the skilled artisan to select menthol, to select eucalyptus oil, to select an effervescent agent that includes an acid and a base and then combine these ingredients in the form of a tablet. Gioffre et al. further fail to teach or suggest dissolving such a tablet in water.

Andersen does not cure the deficiencies of Gioffre et al. Andersen does not teach or suggest a tablet that includes menthol and eucalyptus oil. In addition, nothing in Andersen directs the skilled artisan to select menthol and eucalyptus oil and formulate the same into a tablet. Andersen also does not teach or suggest dissolving such a tablet in water to form a clear solution and then gargling with the clear solution. To the contrary, Andersen expressly states that no premixing of the tablet in a solution is necessary (Andersen, col. 4, lines 9-10). Andersen further explains that the necessary steps include placing the tablet in the mouth followed by an ounce of water and if no water is available, the user's saliva will do (*Id.*, lines 10-13). Accordingly, the skilled artisan would have no reason to formulate a tablet that dissolves to a clear solution --let alone to formulate a tablet to include menthol and eucalyptus oil, dissolve it in water to form a clear solution and then to gargle with the same. For at least these additional reasons claim 34 is distinguishable under 35 U.S.C. § 103 over the proposed combination of Gioffre et al. and Andersen. To the extent this rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the passages in the cited references that are relied upon in reaching the conclusion of obviousness of claim 34. Applicants further respectfully request that the next action provide an explanation as to the manner in which the specific references are being combined and how the alleged teachings in the references render the method of claim 34 obvious.

Applicants note that the December 22<sup>nd</sup> Office action appears to rely on the belief that a tablet somehow derived from Gioffre et al. will necessarily produce "an astringent

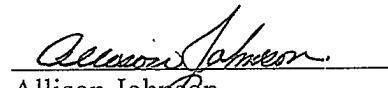
mouthwash effect and desensitizing action, and which form will lend for long lasting plaque control, decay control, anti-microbial action, breath sweetening whitening and thereof.” Applicants can find nothing in Gioffre et al. or Andersen that teaches or suggests that the dentifrice of Gioffre et al. will exhibit these properties if formulated into a tablet and dissolved in water to form a mouthwash. To the contrary, Gioffre et al. disclose only that their dentifrice composition provides an effervescent cleansing. Accordingly, Applicants respectfully request clarification as to the meaning and importance of the statements contained in the December 22<sup>nd</sup> Office action regarding a “resulting mouthwash,” the basis for determining that the “resulting mouthwash” would exhibit the described properties, how the “resulting mouthwash” results from the combination of references, and the identity of the references (including the passages therefrom) that are being relied upon to achieve “the resulting mouthwash.”

There being no further rejection of record, Applicants submit that the claims now pending in the above-captioned application are in condition for allowance and respectfully request action in accordance therewith. Applicants further respectfully invite the Examiner to telephone the undersigned should a teleconference interview facilitate prosecution of the above-captioned application.

The Commissioner is hereby authorized to charge any additional fees that may be required and to credit any overpayment to Deposit Account No. 501,171.

Respectfully submitted,

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